



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/562,469

05/31/2006

Masato Miyake

690121.405USPC

8185

500

7590

08/07/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

08/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,469	Applicant(s) MIYAKE ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-127, 133 and 136-144 is/are pending in the application.
- 4a) Of the above claim(s) 1-127 and 144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 133 and 136-143 is/are rejected.
- 7) ☐ Claim(s) 133 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Status of the Claims

1. Claims 1-127, 133, and 136-144 are pending.

Claims 1-127 and 144 are withdrawn

Claims 133, and 136-143 are rejected.

Claim 133 is objected to.

Terminal Disclaimer

2. The terminal disclaimer filed on 18 June 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S.

Application Number 11/630,814 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 18 June 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

4. The objection to the specification in the Office action mailed 18 March 2009 is withdrawn in view of the amendment to the specification filed 18 June 2009.

Claim Objections

5. Claim 133 is objected to because of the following informalities: In step e), the term environment is misspelled. In step f) the term "data" should be inserted after the first occurrence of the term "experimental." Appropriate correction is required.

Art Unit: 1631

Claim Rejections - 35 USC § 101

6. The rejection of claims 128-135 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter in the Office action mailed 18 March 2009 is withdrawn in view of the arguments and amendment to the claims filed 18 June 2009.

Claim Rejections - 35 USC § 103

7. Modification of the grounds of rejection under 35 U.S.C. 103(a) recited below are required by the amendment filed 18 June 2009.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 133 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. (WO 98/06874, reference AK in the Information Disclosure Statement filed 31 May 2006) in view of Hashino et al. (J. Biochemistry, Vol. 122, pages 490-493 (1997)) in view of Maxwell et al. (DNA Vol. 7, pages 557-562 (1988)).

Art Unit: 1631

The claimed subject matter is an apparatus for obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database. The response is observed over a time course, and the data is from a cell that is immobilized to a substrate by an actin-like compound. The specification shows on pages 260-261 and figure 1 that fibronectin is an actin-like acting substance.

Rine et al. shows in the abstract a process and apparatus that collects data of a plurality of cells. The signals are that of a reporter in response to a stimulation. The signals of the cells are stored in a database. The process and apparatus are further discussed on pages 2 and 4. Rine et al. shows on page 4 that the stimulus can be a pharmacological agent. Figure 1 shows a database of the stored profile results, and an apparatus that executes the process. Rine et al. shows use of the database for comparison queries on page 7. On page 5, Rine et al. shows adjustment of incubation conditions to avoid stress. Rine et al. shows a working example using yeast cells with lacZ fusion reporters on pages 8-17, and is further exemplified on pages 17-19 using different stimuli. Basal response determination is recorded on page 15 which is taken at a particular physical condition of temperature, pH, incubation medium, and osmolarity. Comparison of response profiles are shown on page 16.

Rine et al. does not explicitly show recording cell type, stimulus, or cell culture medium. Rine et al. does not show a time course of response, or a cell that is immobilized to a substrate by an actin-like compound.

Hashino et al. shows in the abstract and especially Table 1 that fibronectin coated substrates improve expression of transfected polynucleotides in cells that have had the polynucleotide added to cells by electroporation.

Art Unit: 1631

Maxwell et al. shows in the introduction on page 557 that introduction of nonreplicating expression vectors to cells by electroporation results in transient expression of the introduced polynucleotide. Figure 1 shows a time course of measurements of the vector-encoded luciferase activity. Figures 1 and 2 show that transient expression in the system used by Maxwell et al. peaks at about 20 hours. Maxwell et al. shows in the results section on page 559 that many different cell lines can be analyzed by their technique, although the maximum expression time varied with the type of cell that was tested.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include in the recorded profile data of Rine et al. the data of the experimental cell type, culture medium, and stimulus to aid in comparison to other profiles because Rine et al. shows comparison of the determined profiles with other profiles and knowing what the cell type, culture, and stimulus is essential to comparison of the stimulus results with other stimulus results. It would have been further obvious to use fibronectin-coated substrates for analysis of cells subsequent to electroporation with an expression vector because Hashino et al. shows that such coated substrates improve expression of electroporated expression vectors. It would have been further obvious to measure a time course of expression subsequent to electroporation because Maxwell et al. shows that transient expression from expression vectors peaks at a time subsequent to electroporation, and that the time of maximum expression must be empirically determined for the cell line that is being studied.

10. Claims 136, 137, 140, and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. in view of Hashino et al. in view of Maxwell et al. as applied to claim 133 above, and further in view of Rosenblum (U.S. Patent Application Publication No. 2002/0055935).

Art Unit: 1631

The claimed subject matter is an apparatus for obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database. The response is observed over a time course, and the data is from a cell that is immobilized to a substrate by an actin-like compound. A request is received for a comparison search with a profile of a requester with the profiles in a database, searching the database, and a result is provided of the search to the service requester. In some embodiments the requester requests the comparison via the Internet.

Rine et al. in view of Hashino et al. in view of Maxwell et al. as applied to claim 133 above does not show comparison initiated by a requester, provision of the results of the comparison to the requester, or requesting of a comparison via the Internet.

Rosenblum shows in the abstract and figure 1 an apparatus that queries a database via the Internet. Rosenblum shows in paragraph 10 use of a database of therapeutic agents that is queried by the Internet. Rosenblum shows in paragraph 13 that multiple databases containing profiles may be queried, and data subsets in paragraph 16 of research data pertaining to the agent. Rosenblum shows selection from among multiple databases in paragraph 21. Rosenblum shows types of data in the profiles in paragraph 38 that include results of assays such as effects of agents on a variety of cell components.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the process and apparatus of Rine et al. by use of the biological database query method and apparatus of Rosenblum because Rosenblum shows how access to biological databases by requester may be performed conveniently via the Internet.

Art Unit: 1631

11. Claims 138, 139, 140, 142, and 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. in view of Hashino et al. in view of Maxwell et al. in view of Rosenblum as applied to claims 136, 137, 140, and 141 above, and further in view of Bimson et al. (U.S. Patent Application Publication No. 2001/0034748).

The claimed subject matter is an apparatus for obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database. The response is observed over a time course, and the data is from a cell that is immobilized to a substrate by an actin-like compound. In some embodiments the results are provided to the service requester using a format in the extensible markup language (XML).

Rine et al. in view of Hashino et al. in view of Maxwell et al. in view of Rosenblum as applied to claims 136, 137, 140, and 141 above do not show output in XML format.

Bimson et al. shows in the abstract a process of searching a database and providing the results of the search in XML format. Bimson et al. shows hardware that executes the process in paragraphs 12, 14, and 15.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Rine et al. in view of Hashino et al. in view of Maxwell et al. in view of Rosenblum as applied to claims 136, 137, 140, and 141 above by use of the XML format because Bimson et al. shows use of XML formats as a known and useful format for search results.

Double Patenting

12. The provisional rejection of claims 128-133 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 82, 84-87, and 90 of copending

Art Unit: 1631

Application No. 11/630814 in the Office action mailed 18 March 2009 is withdrawn in view of the terminal disclaimer filed 18 June 2009.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/
Primary Examiner, Art Unit 1631

jsb